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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,034	05/06/2005	Ratan Chaudhuri	MERCK-3004	9740
23599 7590 02/07/2007 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			EXAMINER ARNOLD, ERNST V	
			ART UNIT	PAPER NUMBER
			1616	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/07/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/534,034	CHAUDHURI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-14 are pending in the application.

Applicant's arguments filed 10/18/06 have been fully considered but they are not persuasive. Claims 11-14 are new. Applicant's amendment has necessitated a new ground of rejection.

Accordingly, this action is FINAL.

Comment: The metes and bounds of "substantially anhydrous" are in the specification on page 5, lines 15-16.

#### **Withdrawn rejections:**

Claims 1, 2 and 5-8 were rejected under 35 U.S.C. 102(b) as being anticipated by Ghosal U.S. Patent No. 6,124,268. Applicant amended the claims to recite a lower amount of Rutin than disclosed by Ghosal. The Examiner is withdrawing the rejection.

Claims 1-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over (U.S. Patent No. 6,649,150 (filing date 04/11/2002)) in view of Vatter et al. (U.S. Patent No. 6,475,500). Applicant correctly pointed out to the Examiner that the patent and application are assigned to the same assignee. The Examiner withdraws the rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

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ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9, and 11-14 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Ghosal (U.S. Patent No. 6,362,167) and Vatter et al. (U.S. Patent No. 6,475,500).

Applicant claims: an anhydrous composition comprising

(a) an antioxidant blend comprising over 40% by weight of hydrolysable tannins comprising Emblicanin A, Emblicanin B, Pedunculagin and Punigluconin and 0.001% to 0.01% by weight of Rutin,

(b) a substantially anhydrous or non-aqueous liquid vehicle functioning to disperse the antioxidant.

#### **Determination of the scope and content of the prior art**

##### **(MPEP 2141.01)**

Ghosal discloses an extract blend used in a method of blocking free radical processes that comprises by weight 35-55% of Emblicanin-A and Emblicanin B; about 4-15% of Punigluconin; and about 10-30% of Pedunculagin; about 0-15% of Rutin and

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about 10-30% of tannoids of gallic/ellagic acid (Claims 1-3). The Examiner considers instantly claimed preferred amount of Rutin (less than 0.01%) within the range 0 to 15% Rutin specified by Ghosal.

Vatter et al. teach an anhydrous cosmetic composition that improves skin color, texture and feel which is prepared by mixing: DC9040 cross linked elastomer gel (a dimethicone gelling agent); cyclomethicone (a silicone oil); silica, titanium dioxide (a sunscreen agent), iron oxide (Ronasphere LDP); isoeicosane (permethyl 102A); alkyl methicone (DC AMS C30 wax) (a structural agent); iron oxides-silicone coated; and titanium dioxide-silicone coated (Column 30, lines 47-64 and Column 32, lines 5-6). Vatter et al. teach that bismuth oxychloride is a suitable agent to add to the composition (Column 13, lines 9-10). Vatter et al. teach that polyethylene glycol is a suitable humectant to add to the composition (Column 11, lines 60-61). Vatter et al. teach that antioxidants can be incorporated into the compositions of their disclosure (Column 23, lines 55-67)

**Ascertainment of the difference between the prior art and the claims  
(MPEP 2141.02)**

Ghosal does not expressly teach a composition comprising the antioxidant extract blend and a substantially anhydrous or non-aqueous liquid vehicle further comprising a sunscreensing agent or bismuth oxychloride.

The features recited in applicant's claim 3 are noted. The difference between claim 3 and Ghosal is that Ghosal does not expressly disclose 20-35 wt% Emblicanin A and 10-20 wt% Emblicanin B. Ghosal discloses a combined amount of 35-55 wt% of the

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two ingredients, which is sufficient to encompass the combined amounts of said ingredients in applicant's claim 3. Additionally, at for example, 40 wt% total of the two ingredients, as disclosed and suggested by Ghosal, equal amounts of the two ingredients would be 20 wt% each. Hence, given the variability of extract content, which would be expected by the ordinary skilled artisan in this field, the percentages of Emblicanin A and B as set forth in claim 3 would have been fairly suggested from Ghosal's teachings.

The maximum absorbance feature recited in applicant's claim 4 is noted. Nowhere else in applicant's disclosure is this feature explained any further. However, applicant does state: "present invention is applicable to all types of extracts of *Phyllanthus emblica*" (specification page 1, lines 13-14). Applicant also states that the cited reference by Ghosal does in fact disclose extracts of *Phyllanthus emblica* (specification page 1, lines 11-14). Therefore, given that Ghosal's extract contains the same exact antioxidants as required by applicant's claim 1, the analytical characteristics set forth in applicant's claim 4 (dependent on claim 1) are presumed to be characteristics that must necessarily be present in Ghosal's extract and its antioxidants, particularly in view of applicant's statement that Ghosal's extract is suitable and further in view of absence of any other evidence regarding the maximum absorbance disclosure. The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the

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suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

### **Finding of prima facie obviousness**

#### **Rational and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add a sunscreen or bismuth oxychloride, as suggested by Vatter, to the composition of Ghosal and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Ghosal suggests that the formulation can be used for personal care compositions for skin care in the form of solutions, lotions, creams or gels but does not provide guidance on the proper excipients to use in the skin care compositions (Column 7, lines 30-34). Vatter et al. provide guidance on excipients to use in anhydrous cosmetic products, which include antioxidants, sunscreen agents and bismuth oxychloride as discussed above. One of ordinary skill in the art would have sought guidance from Vatter et al. to make anhydrous skin care compositions from the anhydrous composition of Ghosal and produce the instant invention. With respect to the choice of bismuth oxychloride having a particle size of less than 35 microns (80% within range) and a median size of 8 to 20 microns, it is deemed merely a matter of judicious selection of commercially available products, acknowledged by the applicant as Biron (LF®-2000) (page 9, line 15), which is well within the purview of one of ordinary skill in the art.

With respect to the USC 103 rejection above, please note that in product-by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 103 is proper because the "patentability of a product does not depend on its method of production." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). In addition, please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' anhydrous composition differs and, if so, to what extent, from that of the discussed reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**Response to arguments:**

Applicant asserted that the teachings of Ghosal when considered as a whole provide no motivation to use levels of Rutin with the range of 0.001 to 0.01% by weight of the composition. The Examiner cannot agree. Claim language is controlling. The disclosure of Ghosal encompasses the instantly claimed range and Applicant has not demonstrated the criticality of the instantly claimed range.



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Applicant asserted that there is no motivation to combine the compounds of Ghosal with the anhydrous composition of Vatter et al. The Examiner cannot agree. Ghosal suggests formulations of creams and lotions without defining the exact compositions. Vatter et al. remedies this deficiency in Ghosal by teaching cosmetic compositions that improves skin color, texture and feel.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, and 5-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6, 8-35 of copending Application No. 10/616,494. Although the conflicting claims are not identical,

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they are not patentably distinct from each other because the subject matter of the instant invention embraces or is embraced by the subject matter of the copending application. Please note that it is the Examiner's position that it is obvious to one of ordinary skill in the art to mix ingredients at room temperature. Instant claims 1-3 drawn to an anhydrous composition comprising antioxidants and a substantially anhydrous or non-aqueous liquid vehicle are embraced by copending claims 1-4 and 6. Instant claim 5 drawn to a substantially anhydrous or non-aqueous liquid embraces copending claims 8-10. Instant claim 6 drawn to a structural agent embraces copending claims 11-13. Instant claim 7 drawn to a gelling agent embraces copending claims 14-17. Instant claim 8 drawn to a sunscreen agent embraces copending claims 18-24. Instant claims 9 and 12 drawn to bismuth oxychloride embraces copending claims 25-34. Instant claim 10 drawn to a method of producing an anhydrous composition embraces copending claim 35. Instant claim 11 embraces co-pending claim 6 which recites 0.01 to 0.001% Rutin.

One of ordinary skill in the art would have recognized the obvious variation of the instant application over the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

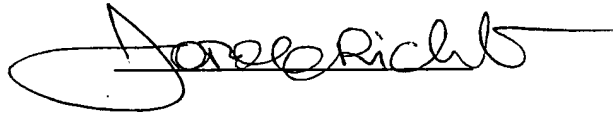
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold  
Patent Examiner  
Technology Center 1600  
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A handwritten signature in black ink, appearing to read "Johann Richter", with a large, stylized loop at the beginning and a horizontal line extending to the right.

Johann Richter, Ph.D. Esq.  
Supervisory Patent Examiner  
Technology Center 1600